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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,130	07/12/2004	Mansoor M. Amiji	NU-598XX	5628
207 7590 08/24/2007 WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			EXAMINER SRIVASTAVA, KAILASH C	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,130	Applicant(s) AMIJI ET AL.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 and 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/12/2004&2/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and amendment filed 11 June 2007 to the Office Action mailed 09 May 2007 is acknowledged and entered.

Informal Matters

2. Recitation of some of the application information data in the header of each page of response and amendment is appreciated. However, upon arrival at the United States Patent and Trademark Office (i.e., USPTO), each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning/ coding and incorporation in to the Electronic File Wrapper (i.e., IFW). Consequently, occasionally papers get separated. To minimize the loss of papers please recite the following information in the header of each page of amendments/ responses or remarks filed with this Office. The information requested below greatly facilitates the prosecution, especially during a telephone conversation/interview with applicant/applicants' representative.

- a. Attorney Docket Number;
- b. First Applicant's name (e.g., Smith Jones et al.);
- c. Correct Group Art Unit Number (e.g., 1657);
- d. Date of Office Action being responded to (e.g., 27 August 2006);
- e. Date of amendment/response (e.g., 27 April 2007); and
- f. Examiner's name (e.g., Dr. Kailash C. Srivastava);

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

3. Please note the correct location of Your application at the United States Patent and Trademark Office (i.e., USPTO) is Art Unit 1657 as notified to you on item Number 2, Page 2 of the Office Action mailed 09 May 2007. To further clarify, the location of your Application at the USPTO is not Art Unit 1641. Therefore, to aid in correctly correlating any papers for this application (i.e., 10/501,130), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

4. Claims 1-25 are present in this case.

5. Claims 15 and 21-23 have previously been withdrawn based on applicants' election in response filed 20 February 2007.

Restriction/Election

6. Applicants' election with traverse of Group I encompassing Claims 1-5 and 9, the group that applicants call "subgroup I" in response filed 11 June 2007 to the election requirement mailed 9 May 2005 is acknowledged and entered. Also entered is applicants' election of whole cell as the catalytic entity, polycarboxylic acid, especially alginate as the anionic carrier polymer and chitosan and other water soluble chitin derivatives as the cationic carrier polymer. Applicants also state that Claims 1-5 and 9 read on applicants' elected inventive and species groups. Applicants' traversal is on the grounds that regardless of the subject matter covered in the newly introduced claim 24, its mere dependency from claim 1 is sufficient for the inclusion of Claim 24 in Group 1 Claims. Applicants, however, explain that the subject matter claimed in Claim 24 despite comprising the subject matter covered in the withdrawn claim 15 is "merely a subset of the limitations present in Claim 1". Further stating that the Examiner has improperly analyzed the claims or "appears not to be applying properly either the principle of dependent claim structure or the principle of claim differentiation" (See Remarks page 9, Lines 1-7), applicants argue that the cross-linking of the respective layers is only in relation to referring a particular embodiment being defined, not to functionality because each one of the Examiner defined three groups are drawn to "immobilized catalytic system".

With regard to limitations present in Claim 24, regardless of the fact that Claim 24 now depends from Claim 1 in response filed 20 February 2007, applicants have also called the limitations in claim 24 "the primary limitations of Claim 15". Since applicants have not elected the Group II invention encompassing Claims 15-23 in their election filed 20 February 2007, the subject matter of Claim 15 now encompassed in Claim 24 is by all means a matter for which applicants have received an action by original presentation and can not therefore be brought back as depending upon another claim from a Group that applicants have elected for further prosecution.

Regarding, applicants arguments related to cross-linking of different layers related only to an embodiment under consideration, rather to the functionality of a given layer, the three layers are different not because of what is being considered at a given time but indeed because of the functionality manifestation of those layers which ultimately determines the stability and overall performance of the immobilized catalytic system.

Each one of applicants' arguments cited *supra* and on Remarks Page 8, Line 10 to remarks Page 10, Line 11 filed 11 June 2007 have been carefully and fully considered but are not persuasive to rejoin all the inventive groups or consider each one of the species in a single invention because:

(i) each one of the distinguishing species and groups have a contribution separate from the other; and (ii) it will be extremely burdensome to examine Claims 1-25 in a single invention. Burden lies not only in the search of U.S. patents, burden also lies in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

7. Claims 1-5 and 9 are examined on merits.

Priority

8. Applicants' claim for priority under 35 U.S.C. § 119(a-d) to PCT/US03/00738 filed 10 January 2003 is acknowledged.

9. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to Provisional U.S. Application Serial Number 60/347,234 filed 10 January 2002 is acknowledged.

Information Disclosure Statement

10. The Information Disclosure Statements (i.e., IDSs) filed 12 July 2004 and 20 February 2007 have been made of record, considered and duly initialed sheets of form USPTO 1449 are enclosed with this Office Action.

Objection To Specification

11. The continuity at page 1 of the disclosure needs to be updated.

Claim Rejections Under 35 U.S.C. § 112

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 4-5 and 9 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation, “derivatives” in claims 4 and 9 is unclear as well as confusing, because this term does not clearly define as to how similar a compound should be of the base compound to be called derivative, i.e. the term does not define the metes and bounds of the claimed subject matter. Appropriate definition is required.

All other claims that directly or indirectly depend from the rejected claims (e.g., Claim 4) are also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 103

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

16. Claims 1-5 and 9 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Moo-Young et al. (U.S. Patent 5,116,747) in view of DeGroot et al. (Enzyme and Microbial Technology, Volume 29, Pages 321-327, 2001).

Claims recite a method to immobilize a catalytic system comprising a carrier layer comprising said catalytic activity mixed with anionic or neutral carrier and additional layer, “screening layer” comprised of a cationic polymer matrix. The two layers are layered in a manner that the catalytic entity does not permeate out of the anionic or cationic layers but the reactant can penetrate through the two layers into the catalytic system and products can freely permeate out of the same system. The catalyst in

said immobilized catalytic system is from the Markush Group consisting of antibodies, enzymes, whole cells, microorganisms, proteins, ribonucleic acids, cellular components, chemical entities, metal catalysts and The anionic polymeric matrix for immobilization is alginate and cationic polymer is chitosan.

Please note that a cell is comprised of cell components (e.g., nucleus, ribosomes, cell walls, cell membranes, endoplasmic reticulum and various macromolecules, e.g., proteins, enzyme encompassed within the term proteins and nucleic acid among others).

Regarding Claims 1-5 and 9, Moo-Young et al. teach a biologically active material, e.g., hybridoma cell immobilized in to droplets of a suspension of polyanionic sodium alginate and polycationic chitosan or chitosan so that the hybridoma cells remain embedded in a membrane comprised of sodium alginate and chitosan. Said immobilized hybridoma cells produce monoclonal antibodies when cultivated in a bioreactor. Moo-Young et al. also teach different permutations and combinations of cationic and anionic polymer matrices with e.g., multiple cations to get different compositions of immobilized biocatalysts (Abstract, Lines 1-23). Note also that said immobilized compositions are in form of capsules or membranes. Moo-Young et al., however, do not teach immobilizing a n enzyme (i.e., a protein).

DeGroot et al teach encapsulation of urease in alginate beads that are protected with chitosan membranes. Thus, urease activity is highly conserved to un-immobilized urease (Abstract). Note also that in the broadest interpretation, said urease may also be present in a cell, wherein said cell is encapsulated in an alginate bead and said bead is layered with a layer of chitosan around it .

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the teachings from Moo-Young et al. according to the teachings from DeGroot et al. to immobilize a biological catalyst, wherein said catalyst is a cell in to an anionic polymeric matrix, e.g., alginate and subsequently have a layer of an cationic matrix, namely chitosan to prevent the biological/enzymatic activity of said catalytic system, because both Moo-Young et al. and DeGroot et al teach immobilization of a biocatalyst (cell or enzyme) in an anionic and cationic polymeric matrix, wherein said matrices are alginate and chitosan respectively.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Moo-Young et al. with beneficial teachings from DeGroot et al. to preserve the activity of a biological catalytic system because each of Moo-Young et al. and DeGroot references teach a biological catalyst immobilized simultaneously in an anionic and a cationic matrix. The instantly claimed invention is also “prima facie obvious over the cited prior art because it is

obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." (*In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted))

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. No Claims are allowed.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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17 August 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128 / 1657